(19) JAPANESE PATENT OFFICE (JP)

(12) Official Gazette for Unexamined Patent Applications (A)

(11) Japanese Unexamined Patent Application
(Kokai) No. Hei 10-151184

(43) Disclosure Date: 9 June 1998

(51)	Int.Cl.[6]	Ident. Symbols	FI		
	A61L 15/16		A61L	15/01	
//	A61K 31/73	ADD	A61K	31/73	ADD

Request for Examination: Not yet requested **Number of Claims: 3** **FD** **(Total of 4 pages)**

(21) Application No.: Hei 8-330432

(22) Application Date: 25 November 1996

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(54) [Title of the Invention] Functional Wound Coating Material

(57) [Abstract]

[Problem] To provide, inexpensively, a material as a wound coating material that has the properties of (1) protection and heat-insulation of wounds, (2) good affinity for the body without causing tissue reactions, (3) absorbing and eliminating exudates and forming a suitable moist environment, (4) having antimicrobial activity, (5) having an analgesic effect and (6) having a wound healing promoting effect, as a result of mixing or applying cotton in which chitin and chitin-cellulose mixed fibers or cotton in which chitin chitosan cellulose mixed fibers and natural, or synthetic fibers are mixed or woven fabrics or non-woven fabrics in unaltered form or hydrophilic colloidal agents manufactured by mixed spinning, blend knitting or blend weaving of said cotton.

[Method of Solution] A functional wound coating material in which regenerated chitin-chitosan cellulose mixed fibers only obtained from chitin-chitosan viscose and cellulose viscose, cotton in which regenerated chitin-chitosan cellulose mixed fibers and natural, man-made or synthetic fibers are mixed, and blend knit or blend woven, woven fabrics or non-woven fabrics or hydrophilic colloidal agents are mixed.

[Claims]

[Claim 1] A functional wound coating material characterized in that it is manufactured by ordinary wet spinning of viscose method artificial fibers from mixed viscose in which chitin-chitosan viscose and cellulose viscose are mixed in desired proportions and in that it is comprised of cotton in which regenerated chitin-chitosan cellulose mixed fibers are applied in unaltered form to ulcerated surfaces of skin or of woven fabric, knit fabric or non-woven fabric manufactured from said cotton.

[Claim 2] A functional wound coating material as described in Claim 1 characterized in that it is comprised of cotton in which regenerated chitin-chitosan cellulose mixed fibers and natural, artificial or synthetic fibers are mixed or of knit fabrics or non-woven fabrics manufactured by mixed spinning, blend knitting or blend weaving of said cotton.

[Claim 3] A functional wound coating material as described in Claim 1 or 2 characterized in that the cotton, knit fabric or non-woven fabric manufactured by Claim 1 or 2 and a hydrophilic colloidal agent are mixed or a hydrophilic agent are applied and are used in unaltered form on the ulcerated surface of skin.

[Detailed Description of the Invention]

[0001]

[Field of Industrial Use] This invention relates to a functional wound coating agent that is used to promote wound healing by applying to ulcerated skin surfaces such as bedsores or scalds cotton in which chitin and chitin-cellulose mixed fibers or cotton in which chitin chitosan cellulose mixed fibers and natural, or synthetic fibers are mixed or woven fabrics or non-woven fabrics in unaltered form or hydrophilic colloidal agents manufactured by mixed spinning, blend knitting or blend weaving of said cotton are mixed or hydrophilic colloidal agents are applied.

[0002]

[Prior Art] Conventionally, wound healing has been classified as primary healing and secondary healing. Primary healing is a mode as in a surgical wound in which the wound surface is bonded and in which a small quantity of granulation tissue is seen so that healing occurs rapidly. The coating material that is used primarily for wounds in primary healing is gauze, with healing occurring without problems as long as there is no microbial contamination of the wound. By contrast, in secondary healing, there is a large loss of tissue, growth of a large quantity of granulation tissue is necessary and a long time is required for completion of the epidermis. Examples of wounds in secondary healing include bedsores and arterial and venous ulcers and further includes skin ulcers as a group, which also includes cuts and scalds.

[0003] The above-described skin ulcers are deep and the course of healing is greatly affected by bacterial infection. Specifically, there are many instances in which cuts and scalds are shallow and clean and in which the only problem is growth of epidermis so that there is considerable tendency toward healing. By contrast, bedsores and arterial and venous ulcers are of various extents, ranging from shallow to deep. The coating material that is used for these wounds is a material that has the functions of protection, heat-insulation and absorption of exudate, substances having an antimicrobial effect and a granulation formation promoting effect being added to them. In addition, it is to be stressed that maintenance of a suitably moist environment for the wound has a positive effect on wound healing.

[0004] Various wound coating materials based on the above-described concept have been used. Specifically, there are gauze and coating materials similar to it, film dressings, hydrocolloid dressings and biological dressings. They all have both advantages and drawbacks. For example, gauze has long been the most widely used coating material. However, it is difficult to maintain a most wound surface with it and it becomes affixed to the wound, damaging the granulation tissue. In order to prevent this, there are products to which an oleaginous ointment is applied. However, this does not completely solve the problem. In addition, water-soluble or oleaginous ointments are frequently used in combination for antimicrobial purposes or for the purpose of promoting formation of granulation. However, in these cases, it is difficult to maintain a moist environment on the wound surface. Film dressings readily retain exudates and can be used on very shallow wounds. Hydrocolloid dressings are highly useful for shallow, clean wounds but cannot be used for wounds accompanied by deep bacterial infections. Pig skin, collagen, alginic acid and chitin-chitosan have been developed as biological dressing products. They too are both useful and have their drawbacks. Specifically, because pigskin is a heterogeneous protein, there is the possibility that immunological rejection reactions will be brought about and it is difficult to use except for wounds that are shallow and for which the healing period is short. Although this possibility is less for treatment with collagen, there is the possibility that immunological reactions will occur, and,

because it readily undergoes fusion, it is difficult to use it except for fairly shallow wounds. Alginic acid has a high water-absorbing capacity and promotes healing by formation of a moist environment due to gelation. However, in actuality, gelation of calcium salts does not easily occur and become affixed to the wound when there is only a small quantity of exudate.

[0005] There are chitin-chitosan wound healing materials in the form of chitin-chitosan cotton sponges or non-woven fabric for human and animal use (Japanese Patent Application Early Disclosure No. Hei 5-92925 [1993]). The characteristics of wound healing materials in which chitin-chitosan cotton, sponges or non-woven fabrics are used are as follows. (1) They have good affinity for the body and cause essentially no tissue reactions. (2) They have high protein absorbing capacity. (3) They are effective for growth of granulation tissue. (4) They have antimicrobial capacity (chitin). (5) Because they have an analgesic effect, they provide extremely good results in a broad range of scalds and in the field of veterinary surgery. However, they are expensive and their capacity is decreased in moist environments. For these reasons, there is the problem that they are not in widespread use in human subjects.

[0006]

[Problems the Invention is Intended to Solve] As the result of research on the above described problems, it was ascertained that the following characteristics are required for wound coating materials. Specifically, (1) that they have protective and heat-insulating effects on wounds. (2) That they have good affinity for the body and that they do not produce tissue reactions. (3) That they absorb and eliminate exudates (drainage) and that they form a suitable moist environment. (4) That they have antimicrobial activity. (5) That they have an analgesic effect. (6) That they have wound healing promoting effects such as granulation tissue growth. (7) That they are inexpensive. This invention has the objective of providing materials having these characteristics and which are inexpensive.

[0007]

[Means for Solving the Problems] This invention is a functional wound coating material which uses cotton, cloth or non-woven fabric comprised of regenerated fibers of chitin-chitosan, which has the above-described characteristics and which promotes healing by regulating the environment of the wound. Specifically, the first [invention] is a functional wound coating material characterized in that it is manufactured by ordinary wet spinning of viscose method artificial fibers from mixed viscose in which chitin-chitosan viscose and cellulose viscose are mixed in desired proportions and in that it is comprised of cotton in which regenerated chitin-chitosan cellulose mixed fibers can be applied in unaltered form to ulcerated surfaces of skin or of woven fabric, knit fabric or non-woven fabric manufactured from said cotton. The second [invention] is a functional wound coating material as described in Claim 1 characterized in that it is comprised of cotton in which regenerated chitin-chitosan cellulose mixed fibers and natural, artificial or synthetic fibers are mixed or of knit fabrics or non-woven fabrics manufactured by mixed spinning, blend knitting or blend weaving of said cotton. The third [invention] relates to a functional wound coating material as described in Claim 1 or 2 characterized in that the cotton, knit fabric or non-woven fabric manufactured by Claim 1 or 2 and a hydrophilic colloidal agent are mixed or a hydrophilic agent are applied and are used in unaltered form on the ulcerated surface of skin.

[0008] The method of manufacture of the mixed fibers of regenerated chitin-chitin cellulose of this invention in which chitin-chitosan viscose and cellulose viscose are mixed in any desired proportions and are manufactured by the ordinary viscose artificial fibers wet spinning method mixing from the mixed viscose is the method described in Japanese Patent Application No. Hei 8-71199 [1996] of 1 March 1996 which was submitted as a joint application by the two applicant companies, the Omikenshi Company (Ltd.) and the Koya Chemical Company (Ltd.). In this case, in this invention, the proportion of the constituents, the chitin-chitosan constituent and the cellulose fiber constituent, in the cotton, cotton cloth, woven fabrics and non-woven fabrics which are the final products obtained by the above described invention of the above described Japanese Patent Application No. Hei 8-71199 [1996] as function wound coating materials may be any desired proportion. The mixture ratio (referred to as the DAC ratio) of chitin-chitosan in the final product as described in the above described Japanese Patent Application No. Hei 8-71199 [1996] should be 15 to 75%, preferably, 18 to 70%, and, more preferably, 25 to 70%.

[0009]

[Action] This invention, as described above, is cotton, cotton cloth, woven fabric and non-woven fabric from mixed fibers of regenerated chitin-chitosan and regenerated cellulose in which chitin-chitosan viscose and cellulose viscose are mixed in any desired proportion and in which mixed viscose is manufactured by the viscose artificial fibers wet spinning method. The functional wound coating material of this invention has greater strength and exudate absorbing capacity than cotton, woven fabric and non-woven fabric of fibers comprised only of chitin and chitosan. They display flexibility, and, because they can be mass produced, they can be less expensive. They further have the additional important functions as wound coating materials provided by the

chitin-chitosan of protein absorbing capacity, capacity for promotion of granulation and epidermis formation, antimicrobial activity and analgesic action. In addition, as described above, they have the advantage that they can be adapted to various types of wounds by adjusting the chitin-chitosan content and the ratio of chitin and chitosan (degree of deacetylation). Also, addition of properties or growth is possible by mixture with other tissues.

[0010] Further, the wound coating material comprised of these fibers of cotton, woven fabric and non-woven fabric can be combined to make a single entity. For example, materials in the form of sheets can be laminated in several layers. In this case, the sheets may be of the same or different thickness, fiber arrangement, composition and elasticity. By this means, active use can be made of the characteristics of the various layers. For example, the composition of the cotton, cotton cloth, woven fabric or non-woven fabric that is in contact with the wound can be varied . By using a material that is pliable and that has a high water-retaining capacity, a moist environment can be maintained. By placing a material exhibiting elasticity in the top layer, protection of the wound can be strengthened. By these means, the functionality of the wound coating material of this invention can be increased.

[0011] In addition, a hydrophilic colloid is used in hydrocolloid dressings. It has high water-absorbing capacity, undergoes gelation due to absorption of water and forms a moist environment. Because promotion of granulation growth occurs in this environment due to dissolution of necrotic tissue by leukocytes and proteolytic enzymes, treatment by bacteria or maintenance of growth factors, this has been found to be extremely advantageous in the treatment of skin ulcers. Consequently, by mixing them with the cotton, woven fabric or non-woven fabric of this invention, the marked effects are displayed of further increasing such characteristics of the chitin-chitosan cellulose fibers of this invention as effective absorption and elimination of exudates as well as protein adsorption, their action in promotion of granulation formation and their antibacterial action.

[0012]

[Mode of Execution of the Invention] This invention relates to a wound coating material in which regenerated chitin-chitosan cellulose fibers that are manufactured by the method of Japanese Patent Application No. Hei 8-71199 [1996] with a chitin-chitosan and cellulose DAC ratio of 15 to 75% are used, in which cotton, woven fabric or non-woven fabric, these materials and natural fiber cotton, cotton mixed with sheeting of artificial fibers or synthetic polyester fibers and woven fabric or non-woven fabric made from it are used in unaltered form or are mixed with a hydrophilic colloid.

[0013]

[Working Examples] We shall now present working examples of this invention.

[Working Example 1] Cotton and cotton cloth containing 20 wt% of chitin-chitosan and 80 wt% of cellulose were manufactured from regenerated chitin-chitosan cellulose fibers manufactured on an industrial scale in accordance with Japanese Patent Application No. Hei 8-71199 [1996] and were used in treatment as functional wound coating materials. The subjects were selected as described below. These fibers were used in 7 cases of 77 to 89 years of age (average, 84.9 years). The wound was bedsore in 6 cases and trauma in 1 case.

Method of Use

The fibers of this invention were formed into cotton or cotton cloth (referred to as sheets). When cotton was used, the wound was filled with or coated by a suitable quantity. When sheets were used, they were attached to the wounds. In either case, they were covered by sterilized gauze. The cotton and sheets that were used were replaced at intervals of 2 to 3 days. At this time, the wounds were washed with physiological saline solution and disinfectants were not used. In addition, systemic and local administration of antibiotics and local administration of medicines to the wounds were not performed in any cases. The states of use and results of use of the cotton and sheets are shown in [Table 1].

States of Use

There was good attachment of fibers to the wounds and there was good absorption of exudates. For this reason, wound cleansing was effective and there was good growth of granulation and epidermis.

Effects of Treatment

As shown in the table, cures were achieved in all cases except Case 6. Case 6 was a patient who died because of complication of pneumonia on the 13th day. The observation period was 12 to 42 days (average, 25.7 days). No side effects were thought to be due to this wound coating material during the treatment period.

[0014]
[Table 1]

Case	Age	Sex	Site	Stage	Underlying Disease	Material Used	Effective-ness	Observation Period
1	86	m	sacrum region	3rd degree	pneumonia anemia	cotton	cure	40 days
2	88	f	left ilium region	2nd degree	sequelae of cerebral hemorrhage	sheet → cotton	cure	42 days
3	85	f	left trochanter major region	2nd degree	diabetes	sheet → cotton	cure	27 days
4	83	f	sacrum region	2nd degree	chronic hepatitis B	sheet	cure	21 days
5	89	f	right shoulder; right trochanter major region	2nd degree 2nd degree	ischemic heart disease	sheet sheet	cure cure	12 days 12 days
6	77	m	right lower leg	3rd degree	Behcet's disease	cotton	reduction	13 days
7	88	f	right lower leg	peeling of epidermis	hypertension; ischemic heart disease	sheet	cure	26 days

[0015]

[Working Example 2] A atypical material of cotton was made with a mixture of a water-soluble or oleaginous ointment and a hydrophilic or hydrophobic polymer alone or a mixture thereof and of the fibers used in Working Example 1. The fibers that were used consisted of 20% chitin-chitosan and 80% cellulose, the hydrophilic colloid agent pectin was mixed with it and it was affixed to the wound in a cotton state. As the result of its use in one case each of second degree and third degree bedsore, there was good absorption of purulent exudate and there was extremely good cleansing of the wounds, with a marked curing effect being obtained.

[0016]

[Working Example 3] A non-woven fabric was manufactured by the spun lace method using regenerated chitin-chitosan cellulose in the same way as in Working Example 1 and the product was used as a functional wound coating material in the same way as in Working Example 1.

[0017]

[Effect of the Invention]

(1) When the functional wound coating material of this invention was used alone or in combination with a hydrophilic colloidal agent, it had the above-described six characteristics, specifically, (a) a protective and heat-insulating effect on the wound, (b) good affinity with the body and did not produce tissue reactions, (c) it absorbed and eliminated exudates (drainage) and formed a suitable moist environment, (d) antibacterial activity, (3) an analgesic effect, (f) wound healing promotion effects such as growth of granulation tissue, and (g), it was inexpensive.

(2) The greatest effects of this invention were that, because cotton, woven fabric and non-woven fabric in which chitin-chitosan fibers and regenerated cellulose fibers are mixed uniformly were used, it was soft, it exhibited high water absorbing capacity due to cellulose and marked wound treatment effectiveness due to both antibacterial activity attributable to the chitin-chitosan and its capacity to promote protein adsorption and granulation-epidermis formation.

(3) There are the advantages that products in which regenerated chitin-chitosan and regenerated cellulose are mixed uniformly can be mass-produced industrially and that they are inexpensive.